

### **REMARKS**

Claims 1 and 13 have been amended. Claim 19 has been canceled. Claims 1-6, 8-11 and 13-18 remain in the application. The applicant respectfully request entry of this minor amendment that merely clarifies that the force transmitting layer only extends between the first molar on the right side of the arch and a first molar on a left side of the arch of a custom-made mouthguard, and does not require additional searching.

Claims 1-11, 13-19 and 25-26 were rejected under 35 U.S.C. §103(a) as being obvious over Kallestad et al. (U.S. Patent 3,943,924) in view of Jones et al. (U.S. Patent 5,746,221) and Daskalon et al. (U.S. Patent 6,533,969). The Applicant respectfully traverses this rejection.

The Office indicated that the affidavit submitted by the Applicant is insufficient to overcome the rejection under 35 U.S.C. §103(a) since the Applicant did not provide evidence to support Applicant's assertion regarding the arrangement of the force transmitting layer in the outer wall and the use of the fibrous material for the force transmitting layer; support of the success of the product in reducing or preventing injury; or support for the assertion of the success of the product in preventing or reducing injury.

The Applicant respectfully disagrees with the Office's characterization of this affidavit. First of all, the affidavit establishes the level of skill in the art to solve this problem, which in this case is one familiar with diagnosing and treating sports injuries. The Applicant is a dentist with forty years of clinical experience in treating sports injury. The Affidavit established that the problem is widely known, existing mouthguards are large, cumbersome and interfere with breathing. The novelty of this invention is a custom mouthguard that is lightweight, thinner, and effective in preventing injury due to the novel placement of the force transmitting layer and use of the long fibers embedded in a resin matrix to distribute any applied force along the

longitudinally extending fibers, to reduce the amount of the applied force transmitted through the arch of the user. This invention solves the wearability problem of the prior art, since the athlete can wear the mouthguard and still breathe, talk and perform.

The Office discounts the use of this custom mouthguard by basketball players, and makes the statement that mouth injuries and concussions are rare basketball injuries. The Office did not consider that professional hockey players use this device. The Applicant respectfully submits that the Office is incorrect in its assumption regarding concussions and the use of mouthguards and lacks the requisite skill in the art to make such an assertion. The Office is not considering the main reason why athletes do not wear mouthguards – they are uncomfortable and the athlete can not breathe. To perform at a peak level, an athlete needs to breathe. This is why professional or college sport teams, like the NHL, or NCAA basketball, do not require that players wear mouthguards, despite known risks. Although the Examiner may doubt the benefit of a mouthguard in preventing concussive injury, the Examiner's opinion does not represent that of one skilled in the art of sports injury. The Applicant provided some examples of successful use of this device, and could provide testimonials from athletes or trainers familiar with the use of the device.

The Kallestad reference discloses a mouthguard having an insert material with an arcuate shape and positioned in an inner wall of the mouthguard behind the tooth. The Kallestad reference also discloses that the insert material serves as a brace behind the tooth, so that a force applied to the tooth is absorbed by the front layer, transmitted through the tooth and then dispersed by the insert material. The Kallestad reference is deficient since it does not disclose that the insert material is positioned in front of the tooth, to transmit an applied force across the

front surface of the teeth before the force reaches the tooth, and to reduce the force before it reaches the tooth.

The Jones reference discloses a cold formed mouthguard of expanded PTFE material that includes an outer shell, a force absorbing layer, and an insert. The Jones reference is distinguishable since it discloses a cold formed mouthguard and does not disclose a custom-made, moldable, settable mouthguard. In fact, the specification of Jones distinguishes between the various styles of mouthguards, including stock, mouth-formed and custom-made (column 1, lines 17-67 to column 2, lines 1-4 and 55-64), and specifically teaches away from a custom-made mouthguard. The Jones reference also discloses an insert positioned transversely in a lower portion of the outer wall of the mouthguard, and that the insert extends longitudinally the entire length of the mouthguard. The Jones reference is distinguishable from the present application since the insert extends over the entire length of the mouthguard in a longitudinal direction, and only a lower portion of the outer wall in a transverse direction. The Jones reference does not disclose that the insert material only extends between the first molars on each side of the arch in a longitudinal direction, or only between the incisal and cervical portion of the tooth in a transverse direction.

The Daskalon reference merely discloses a bonding material layer of fibers in a resin matrix that functions to cover a ceramic bar. The Daskalon reference merely discloses that the bonding layer functions to allow the dental appliance to be shaped, or for another layer to be bonded thereon. The Daskalon reference is deficient since the bonding layer functionally provides a bonding surface within a dental restoration, and is not a force transmitting layer in a mouthguard.

As reiterated by the Supreme Court Decision in *KSR International Co. v. Teleflex*, 1727, 1734 82USPQ 2d 1785, 1391 (2007), the factual inquiries of *Graham v. John Deere* still control. That is, determining the scope and content of the prior art; ascertaining the difference between the claimed invention and the prior art; and resolving the level of ordinary skill in the pertinent art. The court also stated that secondary considerations may also be utilized in an obviousness analysis. That Applicant has met each of these inquiries. There has been a long felt need to develop a customized is comfortable and allows the user to breathe and talk while wearing it during an athletic endeavor.

In *Ex parte Carolyn Ramsey Catan*, appeal 2007-0819, decided July 3, 2007, the board stated that “the combination of familiar elements according to known method is likely to be obvious when it does no more than yield predictable results (citing *KSR*, 127 S.Ct at 1739, 82USPQ2d at 1395)

Further, in order to make a *prima facie* case of obviousness, the Examiner must provide an “articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” (*In re Kahn*, 441 F.3d 977, 988 CA Fed. 2006)

The Applicant respectfully submits that the results obtained by combining these references is not obvious since the elements in combination do not perform the same function that each performs separately. Examiner has not met this factual burden of proof and is using the Applicant’s application as a template to combine these unrelated references through a hindsight reconstruction of Appellant’s claims. (*Ex parte Crawford et al.*, Appeal 20062429 decided May 30, 2007). The bonding layer described in the Daskalon reference performs a completely different function than the force transmitting layer in the present application. The insert and outer wall of the Jones reference transmits the forces in a totally different manner than the

present invention. The structure and function of the mouthguard in the Kallestad reference is distinguishable from the present invention.

Therefore, the mouthguard of the present application is not predictable in light of the prior art, since the selected elements of the prior art do not perform the same function in combination as they did separately. The present application discloses a unique combination of a force transmitting layer of a fibrous material in a resin matrix with a force absorbing layer that yields a custom mouthguard that is lighter, less cumbersome to wear, and offers effective protection. The Applicant has previously submitted an affidavit of the inventor stating the advantages of the present invention and the resulting commercial success.

Therefore, the Applicant respectfully submits that claims 1 and 13, and the claims dependent therefrom, are distinguishable over the prior art, since the Office has failed to sufficiently articulate why one of ordinary skill in the art would have been motivated to make the asserted combination.

Based on the above, Applicant submits that the claims are in a condition for allowance, which allowance is respectfully solicited. If the Examiner finds to the contrary, it is respectfully requested that the undersigned in charge of this application be called at the telephone number given below to resolve any remaining issues.

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Respectfully submitted,

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